UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,666	04/19/2006	John Michael Corbett	2913474-003000	7937

84331 7590 11/23/2010

Baker Donelson Bearman, Caldwell & Berkowitz, PC
920 Massachusetts Ave, NW
Suite 900
Washington, DC 20001

EXAMINER
YU, MELANIE J

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
11/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroomdc@bakerdonelson.com
ltapp@bakerdonelson.com
rseward@bakerdonelson.com

Office Action Summary	Application No.	Applicant(s)	
	10/535,666	CORBETT ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-15,21,22 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20,23,24 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 May 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 16-18, 20, 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Remacle et al. (US 2002/0177144).

Werner et al. teach a method of measuring the binding of a first partner in an interaction to a second partner in an interaction, wherein the interaction partners are molecular entities, the method comprising the steps of:

delivering a quantity of the second interaction partner to a reaction well of a device (disc has flow channels, which are reaction wells, par. 13) for attachment of the second interaction partner to an attachment zone of the reaction well (DNA capture probes are bound to the surface of the disc and are therefore delivered to the reaction well, par. 13; capture DNA attached to a layer in the target zone, par. 55), wherein the device comprises:

an opaque temperature controlled chamber having a centrifuge rotor therein (chamber 112 is an optical disc drive and therefore opaque, par. 97, Fig. 1; disc is inside optical disc drive and is temperature controlled, therefore chamber is temperature controlled, par. 160; bio disc drive rotates the disc and therefore has a rotor, par. 9 and rotor can perform centrifugation, par. 13), the rotor having at or near the periphery of the rotor and attached thereto at least one radially positioned (radial fluidic circuit, par. 188; reaction wells are positioned radially near the center of the disc and therefore near the rotor, well 128 near center of disc where rotor is located, Fig. 2C) transparent reaction well (par. 105),

the reaction well having on an upper surface thereof an aperture for the addition of reagents to the reaction well (inlet port, 122, in cap portion which is an upper surface, 116, par. 100, Fig. 2C),

the reaction well further including on an internal surface thereof having at least one attachment zone for the second interaction partner (capture zone 140 is in internal surface of the reaction well 130 and is the attachment zone, par. 104, Fig. 2A),

the well having a sufficient length to provide an area for at least one attachment zone (well contains an attachment zone 140 and therefore has sufficient length to provide an area for the attachment zone, par. 104, Fig. 2A) and

an area positioned at the end of the well into which the solutions which are applied to the second interaction partner can be displaced by centrifugal force (solutions are displaced by removing unbound components by centrifugal force, par. 13-14; return channel, 132, is connected to the end of the flow channel well, 130, and is where solutions are displaced upon centrifugation, par. 8 and 109);

a system for detecting light emitted by an indicator molecule (par. 44 and 46); and

a means for controlling the operation of the rotor (par. 7);

adding a solution comprising a quantity of the first interaction partner to the attachment zone (test sample is injected into the flow channel, and contacted with the capture DNA, par. 84) and incubating at a temperature for a time sufficient to allowing binding of the first interaction partner to the second interaction partner (par. 137);

rotating the device rotor at a speed sufficient to displace the solution comprising unbound first interaction partner from the attachment zone (after hybridization, disc is rotated to clear the target zones of unattached sample and labels, par. 84); and

measuring the amount of the first interaction partner bound to the second interaction partner via fluorescence of an indicator molecule bound thereto (par. 62).

Although Werner et al. do not specifically teach the attachment zone being at the end of the well closest the axis of the rotor, the attachment zone taught by Werner et al., 140, Fig. 2B is contains portions that are at the inner most portion of the well (attachment zone, 140, closest to inlet, 122, Fig. 2B). The inner most portion of the well of Werner et al. is closest to the center (inner circle) of the disc shown in Fig. 2B, which is where the rotor from the optical disc drive is placed. Therefore Werner et al. contains attachment zones in the portion of the well that is at the end of the well closest the axis of the rotor.

Werner et al. fail to specifically teach a means for controlling the temperature of the chamber.

Remacle et al. teach a temperature controlled chamber having a centrifuge rotor (par. 60 and 94) and a reaction well having an attachment zone for a specific interaction partner (DNA capture sequences, par. 144), wherein a target is to be hybridized to the attachment zone (par. 145) and a means for controlling the temperature of the chamber being a Peltier type system, which can also be a cooling system (Peltier type system, par. 145-146), in order to provide DNA hybridization in a chamber.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method taught by Werner et al., a means for controlling the temperature of the chamber as taught by Remacle et al., in order to optimize the rate of reaction, sensitivity and specificity of hybridization and detection.

With respect to claim 17, Werner et al. teach the first and second interaction partners being a nucleic acid and a nucleic acid (analytes are DNA and capture molecules are DNA, par. 50 and 53).

Regarding claim 18, Werner et al. teach the first interaction partner delivered as a solution containing a buffer (par. 117) and the second interaction partner delivered as a solution containing a hybridization buffer (par. 125).

With respect to claim 20, Werner et al. teach carrying out the displacement step at a speed of 2000 rpm and 5000 rpm (par. 140), which is encompassed by the recited greater than 500 rpm.

Regarding claim 23, Werner et al. teach the indicator molecule being a cyanine dye, which is an intercalating dye (par. 62).

2. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Remacle et al. (US 2002/0177144).

Werner et al. in view of Remacle et al. teach carrying out the step of adding a solution comprising a quantity of the first interaction partner with the rotor rotating (par. 83), but do not teach the specific rpm of the rotating rotor. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 19 are for any particular purpose or solve any stated problem, and the prior art teaches that the rpm may be varied to assist with mixing (par. 83). Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the biodisc art.

3. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Remacle et al. (US 2002/0177144), as applied to claims 16 and 23, in view of Gjerde et al. (US 6,210,885).

Werner et al. in view of Remacle et al. teach the indicator molecule being an intercalating dye of cyanine, but fail to teach the dye being Sybr green.

Gjerde et al. teach a DNA binding dye of either cyanine or Sybr green (col. 8, line 53-col. 9, line 8), in order to provide detection of a DNA complex that is reversibly labeled.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the dye of Werner et al. in view of Remacle et al., Sybr green as taught by Gjerde et al. One having ordinary skill in the art would

have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected signal would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

4. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Remacle et al. (US 2002/0177144), as applied to claim 16 further in view of Gordon et al. (US 2002/0098528).

Werner et al. in view of Remacle et al. teach measuring fluorescence, but fail to teach the measuring step while the rotor is rotating at a speed of at least 500 rpm.

Gordon et al. teach moving an incident beam for detection in a detection chamber by rotating a biodisc about an axis (par. 19), in order to provide perpendicular scanning of the detection chamber.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Werner et al. in view of Remacle et al., rotating the biodisc as taught by Gordon et al., in order to provide fast detection of bound analyte.

Although Werner et al. in view of Remacle et al. further in view of Gordon et al. do not specifically teach the rotating speed being at least 500 rpm. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 26 are for any particular purpose or solve any stated problem, and the prior art teaches that the rotating speed may be varied in order to control the speed of detection. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the biodisc art.

5. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Remacle et al. (US 2002/0177144), as applied to claim 16, further in view of Almogy (US 6,236,454).

Werner et al. in view of Remacle et al. teach at least one reaction well having multiple attachment zones and measurement of the amount of the interaction partner bound to the second interaction partner via the fluorescence of an indicator molecule (148, Fig. 3; par. 12 and 67), but fail to teach detection using multiple detectors.

Almogy teaches detection of fluorescence in multiple regions (spots) using multiple photodetectors (multiple spots and one photodetector per spot, col. 2, line 56-col. 3, line 5), in order to resolve sufficiently small pixels by having the ability to place detectors at non-oblique angles.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Werner et al. in view of Remacle et al., multiple photodetectors with one photodetector per detection region as taught by Almogy, in order to increase the detection rate of a detection system.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Remacle et al. (US 2002/0177144), as applied to claim 16, further in view of Yasuda et al. (US 6,093,370).

Werner et al. in view of Remacle et al. teach a Peltier device that is a heater and controlling the temperature of a chamber, but fail to teach it linked to a temperature sensor.

Yasuda et al. teach a Peltier device for heating a hybridization area linked to a temperature sensor (col. 19, lines 7-23), in order to control the surface temperatures of hybridization areas.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach to the Peltier device taught by Werner et al. in view of Remacle et al., a temperature sensor as taught by Yasuda et al., in order to provide accurate temperature control for hybridization.

Response to Arguments

7. Applicant's arguments with respect to claims 16-29 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the limitation requiring a means for controlling the

temperature of the chamber and new claims 28 and 29 requiring the new limitations of a heater and cooling system.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641